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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,730	03/05/2002	Graham Davis	215105.00800	8527

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,730	DAVIS ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-36 and 56* is/are pending in the application.

4a) Of the above claim(s) *46 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-36 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20092005*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and arguments filed 22 September 2005 have been entered. Claim 1 has been cancelled.

Withdrawn Rejections

2. Rejection of claims 1-36 and 56 have been withdrawn in light of applicant's arguments.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 5, 14, 17, 18, 19, 30, 34 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Schnipelsky et al. (US 5,229,297).

Schnipelsky et al. teach a cartridge (10, Fig. 1) comprising: a sample holding chamber for receiving a sample and retaining the sample (26, Fig. 2; col. 13, lines 30-40); a first conduit connected to the sample holding chamber (channels 44, 54 and 40 comprise a first conduit, Fig. 1; col. 10, lines 47-61); at least one analyte sensor, wherein the sensor comprises an analyte responsive surface and the surface is within the first conduit (detection site, 40, Fig. 1 is within first conduit; col. 7, lines 38-43; col. 12, lines 36-48); a second conduit, which is connected to the first conduit (48, second conduit, connected to first conduit, 44,54 and 40, Fig. 1; col. 10, lines 47-61); a valve connected to an opening in the first conduit, wherein the valve is closed by

contact with the sample (check valve present in first conduit, col. 10, lines 43-46; check valve closes upon contact with sample moving back through the conduit, col. 14, lines 42-49); and a pump capable of displacing the sample from the holding chamber into the first conduit, the pump further capable of displacing the fluid from the second conduit into the first conduit (cuvette is flexible and pumps fluid into channels when depressed, col. 10, line 62-col. 11, line 10). Although Schnipelsky et al. do not specifically teach a second conduit capable of fluid retention, the conduit does not appear to require any further properties to retain fluid, and therefore the conduit of Schnipelsky et al. would be capable of retaining fluid.

Claim 5 fails to recite any structural limitations required in order for the cartridge to be single use. Therefore, since the cartridge of Schnipelsky et al. teaches the structural limitations recited in claim 2, the cartridge is capable of being used only once prior to disposal.

Regarding claim 14, Schnipelsky et al. teach at least one constriction to control fluid flow within the first and second conduits (pinch point, col. 12, 19-35).

With respect to claim 17, Schnipelsky et al. teach a third conduit connecting the second conduit to an overflow chamber (third conduit 42, connects both first and second conduit to an overflow chamber 43, Fig. 2; col. 10, lines 39-45), but does not exclude connection of the second conduit to the third conduit.

Regarding claim 18, Schnipelsky et al. teach a pump being a flexible diaphragm (26, 30, Fig. 1; flexible compartments, col. 9, line 63-col. 10, line 12).

With respect to claim 19, Schnipelsky et al. teach the analyte-responsive surface comprising an antibody (biotin, col. 6, lines 45-49; col. 7, lines 39-43).

Regarding claims 30 and 34, Schnipelsky et al. teach at least one analyte sensor formed on a substantially planar surface (40, Fig. 2) and mobile microparticles capable of interacting with the analyte and further comprising means for localizing the particles to the at least one sensor (col. 6, lines 49-60).

Regarding claim 56, Schnipelsky et al. teach the sample holding chamber further comprising a closure means (temporary seal, 46, Fig. 1; col. 10, lines 50-52).

Claim Rejections - 35 USC § 103

4. Claims 3, 6-8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297), as applied to claim 2, in view of Chemelli (US 5,254,479).

Schnipelsky et al., as applied to claim 2, teach a cartridge comprising: a sample holding chamber, a first conduit, at least one analyte sensor, a second conduit, a valve and a pump. However, Schnipelsky et al. fail to teach means for inserting at least one air segment into the first or second conduit.

Chemelli teaches a means for inserting at least one air segment into a first or second conduit (col. 4, lines 39-44; col. 5, lines 11-23, can be first or second conduit because roller continues to next location which contains an air pocket, the air pockets of each location are released, and therefore air pockets are inserted into both the first and second conduits (col. 5, lines 11-23), in order to control incubation time.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Schnipelsky et al., means for inserting at least one air segment into the first or second conduit as taught by Chemelli, in order to prevent interference of air pockets or bubbles with the detection chamber.

With respect to claim 12, Chemelli teaches a pneumatic means for displacing air from the air sac into the second conduit (col. 5, lines 11-23).

5. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297) in view of Chemelli (US 5,254,479), as applied to claim 3, and further in view of Zelin (Us 5,821,399).

Schnipelsky et al. in view of Chemelli, as applied to claim 2, teach a cartridge for sensing at least one analyte with a means for inserting at least one air segment into the first or second conduit, but fail to teach at least one sensor capable of detecting an air-liquid interface.

Zelin teaches a cartridge comprising air segments inserted into conduits (col. 3, lines 34-42) and a conductivity sensor capable of detecting an air-liquid interface (col. col. 4, lines 40-67), in order to displace calibrating fluid and separate calibrating fluid from a blood test sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Schnipelsky et al. in view of Chemelli, a conductivity sensor as taught by Zelin, in order to increase the consistency and reliability of the output measurements by ensuring that all air is out of the detection chamber while liquid reactions are taking place.

6. Claims 10 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297), as applied to claim 2, in view of Opalsky et al. (US 6,438,498).

Schnipelsky et al., as applied to claim 2, teach a cartridge for sensing at least one analyte, but fail to teach a means for metering.

Opalsky et al. teach a means for metering involving a capillary stop in a first conduit in order to adequately fill a sensor channel (col. 10, lines 38-col. 11, line 10).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Schnipelsky et al., a means for metering as taught by Opalsky et al., in order to regulate the amount of volume entering the detection chamber.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297) in view of Wozniak et al. (US 4,781,683).

Schnipelsky et al. teach a cartridge comprising a valve connected to an opening in the first conduit wherein the valve is closed by contact with the sample, but fail to teach the valve being a gelling polymer.

Wozniak et al. teach a closable valve of a gelling polymer closed by contact with the fluid sample (col. 2, lines 52-68), in order to prevent reuse of a syringe.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the one-way check valve of Schnipelsky et al., a gelling polymer closed by contact with the fluid sample as taught by Wozniak et al., in order to provide a low cost one-way valve that does not require mechanical components.

8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297), as applied to claim 2, in view of McNeely et al. (US 6,296,020).

Schnipelksy et al. teach a cartridge comprising a second conduit, but fail to teach a valve in the second conduit.

McNeely et al. teach a valve in a second conduit that is responsive to hydrostatic pressure, wherein the valve is a constriction having a fluid-contacting surface comprising a hydrophobic surface (col. 4, lines 14-20), in order to move fluid through a circuit in a specific manner (col. 1, lines 49-52).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the second conduit of Schnipelsky et al., a valve that is responsive to hydrostatic pressure as taught by McNeely et al., in order to prevent the reagent in the second conduit from reacting with fluid in the first conduit with a valve that does not significantly affect established flow in the channel once it becomes established.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297), as applied to claim 2, in view of Cathey et al. (US 5,503,985).

Schnipelsky et al., as applied to claim 2, teach a compartment comprising dried reagents capable of dissolving in the sample (col. 10, lines 13-16), but fail to teach a portion of at least one conduit comprising at least one dry reagent.

Cathey et al. teach a device with compartment (incubation area) comprising a dried reagent, wherein the dried reagent may instead be in a channel (col. 7, lines 12-19), in order to.

Therefore one of ordinary skill in the art at the time the invention was made would have been motivated to include the dried reagent in a first conduit of Schnipelsky et al. instead of the sample compartment. One having ordinary skill would have been motivated to make such a change as mere alternative and functionally equivalent reagent distribution technique and since only the expected time at which the reagent was distributed would have been obtained. The use

of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on preventing inhomogeneous mixing of reagents with a sample.

10. Claims 21-26, 28, 29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297) in view of Cathey et al. (US 5,503,985), as applied to claim 20, and further in view of Zier et al. (US 4,919,141) and Pourahmadi et al. (US 2002/0055167).

Schnipelsky et al. in view of Cathey et al., as applied to claim 20, teach a cartridge comprising an analyte responsive surface and a conduit comprising at least one dry reagent, but fail to teach the surface comprising an antibody-enzyme conjugate.

Zier et al. teach an antibody enzyme conjugate wherein an enzyme is glucose oxidase (col. 3, lines 35-44) and a substrate of D-glucose (col. 7, line 63-col. 8, line 5), in order to detect diabetes. However, Zier et al. fail to teach motivation to use a D-glucose substrate and glucose oxidase enzyme in the cartridge of Schnipelsky et al.

Pourahmadi et al. teach that cartridges used for DNA detection can also be used for protein capture and detection in a sample (par. 43 and 46), wherein a dry reagent is either one for DNA purification or an antibody-enzyme conjugate (par. 87), in order to provide efficient detection of large sample volumes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the immobilized DNA in the analyte responsive sensor of Schnipelsky et al. in view of Cathey et al., an enzyme substrate of glucose and an enzyme of glucose oxidase in a sample as taught by Zier et al., in order to provide a compact and efficient detection of large sample volumes as taught by Pourahmadi et al.

Regarding claims 25, 26, 28 and 29, Zier et al. teach the blood fluid comprising a substrate for an antibody-enzyme conjugate (col. 6, lines 4-8) wherein the substrate is cleaved to produce an electroactive product (col. 7, line 63-col. 8, line 13). Zier et al. also teach the analyte sensor being an amperometric sensor (col. 4, lines 54-62), with a plurality of mechanical and electrical connections (col. 7, lines 45-62).

Regarding claim 32, Zier et al. teach an. enzyme and a substrate capable of regenerating a product consumed by contact with the at least one analyte sensor, whereby a signal from the sensor is increased (col. 7, line 63-col. 8, line 13).

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297) in view of Cathey et al. (US 5,503,985) and further in view of Zier et al. (US 4,919,141) and Pourahmadi et al. (US 2002/0055167), as applied to claim 26, and further in view of Grundig et al. (US 6,221,238).

Schnipelsky et al. in view of Cathey et al. and further in view of Zier et al. and Pourahmadi et al., as applied to claim 26, teach a cartridge wherein a substrate is cleaved to produce an electroactive product, but fail to teach a substrate of ferrocene.

Grundig et al. teach a ferrocene substrate in order to provide a redox-active label of an antigen (col. 1, lines 58-62).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Schnipelsky et al. in view of Cathey et al. and further in view of Zier et al. and Pourahmadi et al., a ferrocene substrate as taught by Grundig et al., in order to modify increase the sensitivity of amperometric indication of an electrode comprising glucose oxidase.

12. Claims 31 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297), as applied to claim 2, in view of Pourahmadi et al. (US 2002/0055167).

Schnipelsky et al., as applied to claim 2, teach a cartridge, but fail to teach a surface coating that decreases non-specific binding.

Pourahmadi et al. teach a cartridge comprising a surface coating that decreases non-specific binding of a substance (par. 101), in order to prevent adhesion of nucleic acids to a cartridge surface.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Schnipelsky et al., a surface coating that decreases non-specific binding as taught by Pourahmadi et al., in order to minimize non-specific binding and more accurately detect analyte present in the sample in low concentrations.

With respect to claim 36, Pourahmadi et al. teach a filter element interposed between the sample holding chamber and the at least one analyte sensor (par. 51) in order to capture desired analyte.

Therefore, it would have been obvious to include the filter element in the cartridge of Schnipelsky et al. between the sample holding chamber and at least one analyte sensor, and adjacent to the at least one sensor, a filter element as taught by Pourahmadi et al., in order to efficiently capture analyte. The microparticles of Pourahmadi et al. would therefore become concentrated adjacent the at least one sensor.

13. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5,229,297), as applied to claim 34, in view of Nelson et al. (US 6,074,827).

Schnipelsky et al., as applied to claim 34, teach a cartridge comprising a microparticle to localize a DNA strand to the sensor (col. 6, lines 29-43), but fail to teach magnetic microparticles and a magnetic field for localizing the microparticles to the sensor.

Nelson et al. teach a magnetic microparticle and a magnetic field for localizing a microparticle (col. 6, lines 30-45), in order to retain analyte in an enrichment channel.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the particles in Schnipelsky et al., magnetic particles with a magnetic field as taught by Nelson et al., in order to provide a rapid and reliable method of localization of analyte.

Response to Arguments

14. Applicant's arguments with respect to claims 1-36, 46-47 and 56 have been considered but are moot in view of the new ground(s) of rejection.

Claims 46 and 47 will not be rejoined with the product of claims 1-36 and 56 because claims 46 and 47 are drawn to a method of using a product that is not allowable.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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10/14/05